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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,046	11/06/2006	Guguli Abashidze	15447.0001USWO	8865

23552 7590 12/28/2009

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EXAMINER	
MACAULEY, SHERIDAN R	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,046	ABASHIDZE ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *12-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-25 are pending.

Election/Restrictions

1. Applicant's election with traverse of claims 1-11 in the reply filed on August 24, 2009 is acknowledged. The traversal is on the ground(s) that an examination of all claims would not place a serious search burden on the examiner. This is not found persuasive because a search of all claims would require the employment of multiple search strategies, such as the use of divergent search terms in the search. For instance, a search for the method of preparing a product, as is recited in the elected group, requires the use of different search term than a composition comprising the product, as is recited in the nonelected clams. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 12-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups, there being no allowable generic or linking claim.

3. Claims 1-11 are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 7, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 2 and its dependents are rendered indefinite by the recitation of "mixing the liquid from step (e) with a pharmaceutically acceptable auxiliary and said liquid" in lines 3-4 of the claim. It is unclear what the second "liquid" refers to, for instance, it could refer to the liquid recited at the beginning of the quoted passage or some other liquid at another step during the process of claim 1. Applicant is advised that, if the former is intended, the claim could be clarified by deleting the term "and said liquid."

7. Claim 7 is rendered indefinite by the recitation of "the ratio of adsorbent and solution in step (c) is 7-100." It is unclear whether applicant intends for the ratio of adsorbent to solution in step (c) to be 7-100, for the ratio of solution to adsorbent in step (c) to be 7-100, or some other alternative.

8. Claim 10 is rendered indefinite by the term "the medicinal means." This term is not recited in the claims from which the claim depends and it is unclear what applicant intends for "the medicinal means" to comprise.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (US Pat. 2,414,290; document cited in previous action). The claims recite a method of obtaining a liquid medicinal comprising the following steps: (a) treating honey thermally and obtaining a solution, particularly treating the honey at 100 to 160 degrees C; (b) settling the obtained solution, particularly for 22-26 hours; (c) mixing the solution with adsorbent, specifically wherein the absorbent is activated carbon and wherein the ratio of adsorbent and solution is 7-100; (d) settling the solution mixed with adsorbent, particularly for 10-14 hours; and (e) filtering said solution and

thus obtaining the liquid medicinal, specifically wherein the solution is filtered twice. The claims further recite that the mixture is heated before performing step (c).

13. Erickson teaches honey that has been prepared by heating, mixing with an adsorbent (i.e., activated carbon), and filtering the solution to obtain the treated honey preparation (col. 2, lines 24-52). The also reference teaches a method wherein the honey is heated prior to being combined with the activated carbon (col. 2, lines 46-52) and that honey may be heated and settled to allow the solids to precipitate out (col. 3, lines 4-18). The reference also teaches that the honey may be heated at temperatures of about 100 degrees C (col. 3, lines 40-48). Although the reference does not teach all of the claimed steps in a single method to produce the treated honey product, one of ordinary skill in the art would have been able to combine them with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so because Erickson teaches that the techniques for the treatment of honey may be combined depending upon the characteristics of the batch of honey (col. 6, lines 38-75). One would further have been motivated to alter the method based upon the type of honey and would therefore have achieved the claimed settling times in the course of routine experimentation. It would therefore have been obvious to modify the teachings of Erickson to arrive at the clamed method.

14. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. (US Pat. 2,414,290) as applied to claims 1 and 3-9 above, and further in view of Szejtli et al. (US 4,529,608) and Bender (US 3.485,920). The claims recite a

method of obtaining a liquid medicinal comprising the following steps: (a) treating honey thermally and obtaining a solution, particularly treating the honey at 100 to 160 degrees C; (b) settling the obtained solution, particularly for 22-26 hours; (c) mixing the solution with adsorbent, specifically wherein the absorbent is activated carbon and wherein the ratio of adsorbent and solution is 7-100; (d) settling the solution mixed with adsorbent, particularly for 10-14 hours; and (e) filtering said solution and thus obtaining the liquid medicinal, specifically wherein the solution is filtered twice. The claims further recite that the method comprises (f) mixing the liquid from step (e) with a pharmaceutically acceptable auxiliary, such as sodium bicarbonate and wherein the mass ratio of the medicinal means and the pharmaceutical auxiliary is 1:1; and (g) drying and powdering to obtain the medicinal in the form of dry powder. The claims further recite that the mixture is heated before performing step (c).

15. Erickson teaches honey that has been prepared by heating, mixing with an adsorbent (i.e., activated carbon), and filtering the solution to obtain the treated honey preparation (col. 2, lines 24-52). The also reference teaches a method wherein the honey is heated prior to being combined with the activated carbon (col. 2, lines 46-52) and that honey may be heated and settled to allow the solids to precipitate out (col. 3, lines 4-18). The reference also teaches that the honey may be heated at temperatures of about 100 degrees C (col. 3, lines 40-48). Although the reference does not teach all of the claimed steps in a single method to produce the treated honey product, one of ordinary skill in the art would have been able to combine them with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do

so because Erickson teaches that the techniques for the treatment of honey may be combined depending upon the characteristics of the batch of honey (col. 6, lines 38-75). One would further have been motivated to alter the method based upon the type of honey and would therefore have achieved the claimed settling times in the course of routine experimentation. It would therefore have been obvious to modify the teachings of Erickson to arrive at nearly all elements of the clamed method.

16. However, Erickson does not teach mixing the liquid medicinal with a pharmaceutically acceptable auxiliary, drying and powdering the mixture to obtain the medicinal as a powder.

17. Szejtli teaches a method of preparing a dried honey powder by preparing a liquid, mixing the liquid with a powder and drying the mixture to produce a powdered product (abstract).

18. Bender teaches medicaments comprising honey-based products and a mild, edible base such as sodium bicarbonate (abstract, col. 3, lines 13-30).

19. At the time of the invention, a method of preparing a honey-based product comprising nearly all of the elements of the claimed method was known, as taught by Erickson. It was further known that dried honey products could be prepared by methods such as those recited in the claims and that sodium bicarbonate was a useful carrier for honey-based medicaments. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because Szejtli teaches that drying in the presence of a powdered carrier helps to preserve the natural honey aroma of the product. Since Erickson is directed to maintaining and processing food-

quality honey, one of ordinary skill in the art would have been motivated to further process the honey of Erickson using the methods of Szejtli for preservation. Because both references use similar methods to process the honey, the method could have been combined with a reasonable expectation of success. Further, one of ordinary skill in the art would have recognized that sodium bicarbonate would have been a suitable powder for use with a dried honey product because Bender teaches that the additive is compatible with honey and that it has beneficial medical properties. Furthermore, Erickson teaches that basic components are helpful in the preparation of honey products. Therefore one of ordinary skill in the art would have recognized that the components could have been used in the combined method with a reasonable expectation of success. It would therefore have been obvious to combine the teachings discussed above to arrive at the claimed invention.

20. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651